

### Remarks

Claims 1, 5, 15-27, 62, 68, 70, 75 and 76 are pending in the application. Claims 1, 5, 15-27 and 76 have been rejected by the Examiner. Claims 62, 68 and 70 have been allowed. The Examiner indicated that claim 75 is allowable. Claims 4 and 6-14 have been withdrawn from further consideration. Reconsideration and allowance are respectfully solicited.

#### **I. Rejection of claims under 35 U.S.C 102(b)**

The Examiner has rejected claims 1, 15, 18, 21, 23, 27 and 76 under 35 U.S.C 102 (b) as being anticipated by Miesel et al. (US 6,106,477). The Applicant respectfully requests reconsideration and allowance of the claims.

Claim 1 as previously presented recites a system for monitoring tissue condition comprising: a housing configured to be implanted between a first tissue and a different second tissue within the a patient's body, the housing including a first surface located on a first outer side of the housing and configured to rest against the first tissue, and a second surface located on a second outer side of the housing, opposite from the first outer side, configured to rest against the second tissue; a first sensing system proximate to the first surface configured to sense a physiological property of the first tissue proximate to the first surface; a second sensing system proximate to the second surface configured to sense the same physiological property of the second tissue proximate to the second surface; and a processing system in communication with the first and second

sensing systems configured to compute a difference between the physiological property sensed by the first and second sensing systems.

Claim 1 includes the limitation of a housing configured to be implanted against and between the first tissue and a different second tissue. Miesel did not disclose such a feature, and the Examiner did not refer to this feature in the office action. Miesel's device is not configured to be positioned between two different tissues as required by the claim. Rather, Miesel's blood vessel cuff is configured to wrap around a blood vessel; it has a clamp-type structure (see column 4, line 24).

Futhermore, while the passage (column 5, lines 3-7) of Miesel cited by the Examiner on page 9 of the office action emphasizes that the second sensor is a pressure sensor which can be used to measure ambient pressure of gage pressure, it is evident by this passage that second sensor is not in contact with the vessel and does not measure any physiological property of the tissue, as required by the present claim 1. It is also evident that the sensor does not rest against either tissue. The second sensor in Miesel merely measures the ambient pressure and does not measure physiological property of any tissue.

The Examiner further stated that "Additionally, the placement of the device is at the discretion of the user; any similar device may be implanted such that one side rests against one tissue and opposite side rests against a different tissue, as long as it performs the desired function." However, placement of Miesel's device can neither be between two different tissues as the Examiner has suggested, and the device is not structurally or inherently capable of being

positioned in such a manner. Rather, Miesel's device has a clamp-type structure that wraps around a target tissue (such as a blood vessel) in order to work. Unlike the presently claimed device, Miesel's device does not have a plurality of sensors on the outer sides of the structure to be placed against and between two different tissues on opposite sides.

Furthermore, in rejecting claim 1, it appears that the Examiner has misunderstood the claim limitations. Specifically, claim 1 recites a first sensing system that senses the physiological property of the first tissue and a second sensing system to sense the same physiological property of the second tissue that is different from the first tissue, as discussed above. However, on page 2, section 3 of the office action, the Examiner states "a first sensor for sensing a physiological tissue property proximate to the first surface (column 5, lines 54-55); a second sensor for sensing the same physiological tissue property proximate to the second surface (column 5, lines 3-7)". The Examiner's statement does not accurately reflect the limitations of Claim 1. Claim 1 does not require the sensing of the same physiological property of the same tissue at different surfaces as interpreted by the Examiner. Rather the claim includes the limitation of sensing the same physiological property of two different tissues at opposite surfaces. The passage cited by the Examiner (column 5, lines 3-7) does not teach this feature. Rather, the cited passage teaches a second pressure sensor that is not in contact with the blood vessel (the tissue) to measure ambient pressure for calculation of gage pressure. In fact, the passage does not even suggest sensing of the same tissue by the second sensor from the second

surface as alleged by the Examiner. The second sensor is merely used to sense the ambient pressure. This measurement does not include measuring the same physiological properties of the tissue or even a different tissue as required by the claim.

Claim 1 also includes the limitation of a processing system in communication with the first and second sensing systems configured to compute a difference between the physiological property sensed by the first and second sensing systems. This limitation specifically requires measuring the difference between the same property that was sensed from the first tissue and the different second tissue by the first and the second sensors.

While Miesel also discusses differential monitoring of the vessel with sensors 101 and 102 in column 7, lines 53-62 and figure 13, Miesel does not teach sensing of two different tissues. Miesel is not concerned with this critical reading. For example, in the Applicant's invention, sensing the oxygenation of a first tissue and comparing it to that of a different neighboring tissue may serve as an indication that the sensors are operating properly. Specifically, in the event the the oxygenation of one tissue drops or changes drastically, one can compare this oxygenation to that of the neighboring tissue to see whether the oxygenation is really reduced in the tissue area or the sensor is faulty.

M.P.E.P 2131 requires a reference to teach each and every limitation of the claim. Miesel does not teach all of the present claims' limitations. Moreover, even though the rejection was based on anticipation, the applicant respectfully submits that Miesel would not render the present claims obvious. Specifically,

even under an obviousness analysis, all of the claims are not taught and the Examiner's rejection and reasoning is based on hindsight and do not provide any motivation to modify Miesel's device. Even so with obviousness rejection the references by themselves or together must teach every limitation of the claim.

Therefore, Miesel fails to teach each and every limitation of claim 1 as required by M.P.E.P 2131. The prior art to Sun (US 6,122,536), Gord (US 5,999,848) and Hines (US 6,582,365) also fail to remedy the deficiencies of Miesel and hence the claim is allowable over the prior art.

Claims 15, 18, 21, 23, 27 and 76 depend from an allowable base claim and are thus themselves allowable.

## **II. Rejection of claims under 35 U.S.C 103(a)**

The Examiner has variously rejected claims 5, 16, 17, 19, 20, 22, and 24-26 as being obvious under 35 USC 103(a) over Miesel et al. in view of Sun (US Patent 6106477), Gord et al. (US 5,999,848) and/or Hines et al. (US 6,582,365).

Claims 5, 16, 17, 19, 20, 22, and 24-26 are all dependent upon claim 1. As explained above, Miesel does not anticipate claim 1. Neither Sun, Gord et al. and/or Hines et al., either alone or in combination, remedy the deficiencies of Miesel in teaching the missing features of claim 1, as discussed above. Claims 5, 16, 17, 19, 20, 22, and 24-26 are therefore allowable.

### III. Allowable Subject Matter

The Examiner previously allowed claims 62, 68, and 70. As indicated above, however, the rejection of the base claim should be withdrawn. Claim 75 was objected to as being dependent upon a rejected base claim, but stated it would be allowable if rewritten in independent form.

### IV. Conclusion

The Applicant respectfully requests that the Examiner withdraws the finality of the last office action, and submits that the above remarks place this application in condition for allowance, which the Applicant respectfully solicits.

A petition for a three-month extension of time under 37 C.F.C. 1.136 is being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-094.

Respectfully submitted,  
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